IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Judith A. Varner
Serial No.: 09/307,223 Group No.: 1642
Filed: 05/07/99 Examiner: S. Ungar
Entitled: **METHODS FOR DETECTING AND INHIBITING ANGIOGENESIS**

DECLARATION OF DR. VIRGIL L. WOODS, JR. UNDER 37 C.F.R. §1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Dated: February 19, 2002 By: _____
CLIFF CANNON-CIN

Sir:

1. I, Dr. Virgil L. Woods, am the subject of the attached Curriculum Vitae and author of the publications shown on the list attached thereto. On the basis of the information and facts contained in these documents, I submit that I have been, and am, practicing in the field of integrin biology and biochemistry, and am qualified to speak on the level of ordinary skill in these fields.

2. I have read and understand the above-identified patent application, and pending claims as amended in the Amendment And Response which was mailed to the Office on September 5, 2001.

3. Claim 2 recites an agent which "does not substantially interfere with the specific binding of a ligand to an integrin other than $\alpha 5\beta 1$ integrin to its ligand."

4. The Specification teaches that "As discussed for anti-α5β1 antibodies, a peptide that specifically binds α5β1 can be useful in a method of the invention where the antibody binds to α5β1 with at least about a two-fold greater specificity than it binds to another integrin, . . . is more useful if it has at least about a five-fold greater specificity for α5β1, and is particularly useful if it has at least about a one order of magnitude greater specificity for α5β1 than for an integrin such as αVβ3."[1]

Based on this teaching, it is my understanding that Claim 2's term "**substantially**" refers to the exemplary preferred mathematical ranges (*i.e.*, at least about two-fold, five-fold, and ten-fold) for binding of the ligand (as exemplified by a peptide or antibody) to α5β1 integrin, as compared to binding of the ligand to another integrin. From this teaching, it is my understanding that Claim 2's recitation of an agent which "does not substantially interfere with the specific binding of a ligand to an integrin other than α5β1 integrin" means that the agent's interference with the specific binding of α5β1 integrin to a ligand is at least two-fold greater than the interference of the agent with the specific binding of another integrin to its cognate ligand.

5. Claims 80-86, 90-96, and 110-116 recite that the binding of an "agent" to α5β1 integrin is at least two-fold, five-fold, or ten-fold greater than binding of the agent to an integrin other than α5β1 integrin.

6. The Specification teaches that "As disclosed herein, antibody, peptide and nonpeptide small organic molecule antagonists of α5β1 can interfere with the specific binding of α5β1 integrin with its ligands, particularly fibronectin, in vascular tissue, and can reduce or inhibit angiogenesis (see Examples II, III and IV). Such molecules that interfere with the specific binding of α5β1 with its ligands are referred to herein generally as '*agents*.'"[2]

The Specification also teaches that "The term 'antagonist is used herein to mean an *agent*, which can be an antibody, a peptide or a nonpeptide small organic molecule."[3]

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[1] Specification, page 23, lines 5-14.

[2] (Emphasis added) Specification, page 18, lines 7-15.

[3] (Emphasis added) Specification, page 19, lines 24-27.

Based on these teachings, it is my understanding that the term "**agent**" of Claims 80-86, 90-96, and 110-116 is exemplified by an antibody, peptide, and/or nonpeptide small organic molecule.

7. The Specification teaches that "As discussed for anti-α5β1 antibodies, a peptide that specifically binds α5β1 can be *useful* in a method of the invention where the antibody binds to α5β1 with at least about two-fold greater specificity than it binds to another integrin, . . . is more useful if it has at least about a five-fold grater specificity for α5β1, and is particularly useful if it has at least about a one order of magnitude greater specificity for α5β1 than for an integrin such as αVβ3."[4]

Based on this teaching, it is my understanding that one property which makes an **antibody** or a **peptide** "useful" as an antagonist of α5β1 binding to its ligand(s) is that the antibody or peptide binds with at least about two-fold greater, at least about five-fold greater, or at least about ten-fold greater specificity for α5β1 than for αVβ3. From this understanding in combination with my further understanding that an antibody and peptide are examples of an "agent," (as explained in item 6, *supra*), it is my opinion that the inventor contemplated that this desirable property (*i.e.*, relative binding to α5β1 as compared to αVβ3) which makes the exemplary antibodies and peptides "useful" in the claimed methods, is also a desirable property that is contemplated for **any other type of agent**, including the third exemplary type of nonpeptide small organic molecule. In other words, the Specification conveys to me that the inventor contemplated that one desirable property of **any agent** that interferes with the specific binding of α5β1 integrin to its ligand is that the agent (regardless of its type) binds with at least about a two-fold greater, at least about five-fold greater, or at least about ten-fold greater specificity for α5β1 than for αVβ3.

8. Claims 86, 96, and 116 recite that an agent which interferes with specific binding of the α5β1 integrin to a ligand "does not interfere with the specific binding of a ligand to an integrin other than α5β1 integrin."

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[4] (Emphasis added) Specification, page 23, lines 5-14.

9. The Specification teaches that "Particularly useful antibodies for performing a method of the invention are those that specifically bind to an α5β1 integrin. Such antibodies are particularly useful where they bind α5β1 with at least an order of magnitude greater affinity than they bind another integrin, for example, αVβ3 or αVβ5. An anti-fibronectin antibody also can be *useful* in a method of the invention, particularly an anti-fibronectin antibody that interferes with *binding* of fibronectin to α5β1 integrin, *but not to αVβ3 or other integrin*."[5]

Based on this teaching, it is my understanding that one desirable property which makes an **antibody** "useful" in the claimed methods is that the antibody does not interfere with the specific binding of a ligand (such as fibronectin) to an integrin other than α5β1. While this teaching refers to a desirable property of an antibody, it is nonetheless my opinion that this desirable property was contemplated by the inventor to apply to **any agent** because the Specification teaches that antibodies are an example of an agent (as explained *supra* in item 6).

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Dated: 1/2/2002 By: V L Woods MD.

Dr. Virgil L. Woods

[5] (Emphasis added) Specification, page 22, lines 15-19.

CURRICULUM VITAE
January 2, 2002

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PERSONAL AND FAMILY:

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EDUCATION:

1972 B.S., University of California, San Francisco, Major: Medical Sciences
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1979 B.A., University of California, San Diego, Major: Biochemistry

PROFESSIONAL EXPERIENCE:

1974 - 1975 Intern in Medicine, Barnes Hospital, St. Louis, Missouri
1975 - 1976 Resident in Medicine, Barnes Hospital, St. Louis, Missouri
1976 - 1979 Research Associate, Laboratory of Immunology, NIAID-NIH, Bethesda, MD
1979 - 1981 Rheumatology Fellow, University of California, San Diego
1981 - 1988 Assistant Professor of Medicine In Residence, University of California, San Diego
1988 - 1989 Associate Professor of Medicine in Residence, University of California, San Diego
1989 - 1992 Associate Professor of Medicine, University of California, San Diego
1992 - Present Associate Professor of Medicine and Orthopaedics, University of California, San Diego

MILITARY SERVICE:

July 1977 to July 1979 — U.S. Public Health Service
Discharged with rank of Surgeon (Lt. Commander)

MEDICAL SPECIALTY BOARDS:

1978 American Board of Internal Medicine
1991 Subspecialty Boards in Rheumatology

FEDERAL GOVERNMENT PUBLIC ADVISORY COMMITTEES:
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5. Woods, VL Jr, and HG Bluestein. Characterization of neuronal and lymphoid membrane molecules reactive with antisera to SLE cryoglobulins. Arthritis Rheum 24:S81, 1981.

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10. Pischel, KD, HG Bluestein, and VL Woods Jr. Molecular characterization of lymphocyte cell surface proteins reactive with systemic lupus erythematosus (SLE) autoantibodies. Arthritis Rheum 27:S83, 1984.

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